



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances Application: Fresenius Kabi USA, LLC

[Docket No. DEA-392]

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic class, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.34(a) on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. Such persons may also file a written request for a hearing on the application pursuant to 21 CFR 1301.43 on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESS: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/ODW, 8701 Morrisette Drive, Springfield, Virginia 22152

SUPPLEMENTARY INFORMATION:

The Attorney General has delegated her authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b).

Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Deputy Assistant Administrator of the DEA Office of Diversion Control (“Deputy Assistant Administrator”) pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.34(a), this is notice that on June 13, 2016, Fresenius Kabi USA, LLC, 3159 Staley Road, Grand Island, New York 14072 applied to be registered as an importer of remifentanil (9739), a basic class of controlled substance listed in schedule II.

The company plans to import the listed controlled substance for product development and preparation of stability batches.

Louis J. Milione,
Deputy Assistant Administrator.

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